DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NDA 6-488/S-061

Astra Pharmaceuticals
725 Chesterbrook Boulevard
Wayne, Pennsylvania 19087-5677

MAY 26 1999

Attention: Lisa DeLuca, Ph.D.
Regulatory Liaison Director

Dear Dr. DeLuca:

Please refer to your supplementalNew Drug Application dated July 3, 1997, received July 7, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Xylocaine (lidocaine HCL Injection, USP).

We note that the supplement 061 was submitted as "Special Supplement-Changes Being Effected" under 21 CFR 3 14.70 (c).

This supplemental New Drug Applications provide for revisions to the "ADVERSE REACTIONS, Neurologic" section. The following information has been added:

"There have been reported cases of permanent injury to extraocular muscles requiring surgical repair following retrobulbar administration."

We have completed the review of this supplemental application, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted labeling (package insert submitted July 3, 1997). Accordingly, this supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted July 3, 1997).

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed to each application.Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 6-488/S-061 ." Approval of these submissions by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact Susmita Samantha Regulatory Project Manager, at (301)

Sincerely,

Cynthia G. McCormick, M.D.
Director Division of Anesthetic, Critical Care,
and Addiction Drug Products, HFD-170
Office of Drug Evaluation II
Center for Drug Evaluation and Research